

**METHOD AND APPARATUS FOR  
RAPID DEPLOYMENT CHEST DRAINAGE**

This application claims priority benefit under 35 USC  
§ 119(e) from U.S. Provisional Application No. 60/447,110  
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Field of the Inventions

The inventions described below relate the fields of  
general surgery, cardiothoracic surgery, trauma surgery,  
10 combat medicine, and emergency medical services.

Background of the Inventions

Chest drainage tubes are flexible tubes that are  
placed into a patient's chest cavity to allow for drainage  
of fluids following trauma or surgery. These chest tubes  
15 have one or more holes at the distal end through which the  
fluid is evacuated from the chest cavity into the lumen of  
the chest tube. The proximal end of the chest tube  
includes connectors to allow for passage of the drained  
fluids from the lumen of the chest tube into a collection  
20 device or apparatus. The chest tubes or collection  
apparatus typically include features to prevent backflow of  
air into the chest cavity, thus preventing pneumothorax.  
These backflow prevention features include shutoff valves  
and duckbill valves. Typical collection apparatus  
25 comprises gravity fed drains or vacuum or pump powered  
drainage mechanisms.

Chest tubes are typically placed into a patient with  
a stiff trocar mounted to the internal lumen. The trocar

is stiff, relatively pointed at the distal end, and allows for advancement of the flexible chest drainage tube into an incision in the chest wall. The stiff, pointed trocar is useful for initial insertion of the chest tube but becomes  
5 a dangerous instrument once the chest tube is advanced below the level of the ribs. Use of such internal trocars is not appropriate for non-physician insertion because of the inherent danger of heart or lung perforation.

Maintenance of sterility has always been problematic  
10 with chest tubes. Placement of a chest tube, especially in the emergency setting, requires sterile scrub of the incision area and incision into the chest wall with sterile instruments. These incisions are, understandably, difficult to perform aseptically in the field, where the  
15 insertion site may be bloody, dirty or otherwise contaminated. In addition, maintenance of sterility in the area of chest tube penetration into the chest has been difficult as has been the ability to hold the chest tube in position once it has been introduced into the patient. The  
20 use of surgical gloves to maintain sterility becomes problematic since the gloves become contaminated quickly in the typical field environment.

New devices and methods are needed to permit rapid placement of chest tubes by less trained individuals in  
25 contaminated environments. In addition, improved devices and methods of maintaining sterility at the chest tube wound site and holding the chest tube in place are needed.

#### Summary of the Invention

This devices and methods described herein provide for  
30 placement of chest tubes in contaminated environments using

rapid deployment techniques, for maintaining sterility at the penetration site on the patient's chest where the chest tube emerges, and for improved methods of holding the chest tube in place. The present invention is a chest tube that  
5 is provided with a double aseptic package that maintains sterility and cleanliness of the chest tube in contaminated environments. The chest tube includes a cannula with a sharpened distal end and a blunt trocar or nose cone that selectively shields or exposes the sharpened distal end.

10 In another embodiment, a region on the chest tube is configured to allow for maximum friction while gripping the chest tube through the package material. In another embodiment, a region on the packaging is fabricated from gripping material to facilitate pushing the chest tube  
15 inside the packaging. The region on the packaging optimized for gripping the chest tube is optionally fabricated from elastomeric material to facilitate moving the chest tube inside and relative to the inelastic package. In another embodiment, the blunt trocar itself is  
20 shaped so as to penetrate the package without the need of a separate sharp tip. This blunt trocar is also suitable for blunt dissection into the chest wall once the initial incision has been completed.

The chest tube may further include a malleable region  
25 along part or all of its length to facilitate bending of the chest tube into a pre-determined shape. The use of a curved or bent shape on the part of the chest tube facilitates placement beneath the ribs but above the lungs and heart.

30 Another feature of the invention is a patch, disc, plate or membrane of adhesive-faced impermeable material

that is adhered to the site where the wound will be created in the chest wall. The patch may also be coated with materials that have disinfectant properties. The patch also includes straps disposed, for example, in a starburst pattern. Once the site has been swabbed with disinfectant, the disc of material is adhesively placed on the skin at the site of the incision. The incision is now made through the patch of material. This patch serves as a sterile barrier following placement of the chest tube. The straps serve to hold onto the chest tube to maintain its position once placed. The straps are wrapped around the chest tube and adhesively affixed to the shaft of the chest tube after placement, thus securely holding the chest tube to the disc, which is affixed to the chest wall of the patient. The patch is optionally pre-mounted to the chest tube inside the package. In this embodiment, the chest incision is performed prior to attachment of the patch to the patient. In another embodiment, the disc is integral to the inner packaging material so that once the outer packaging material is removed, the patch may be immediately placed against the chest over the region of the incision.

In another embodiment of the invention, a chest tube is designed with an integral tip that permits the chest tube to be advanced out of the package by forcing a fenestration in the package wall or seal. The integral tip may be a cutting member that is selectively exposed by the operator and then retracted following package penetration. This same cutting member may also be used to make the initial incision in the chest wall of the patient. The member that re-protects the cutting edge may be a blunt nose that is suitable for bluntly dissecting the tissue between the ribs. In another embodiment of the invention,

the blunt nose is configured to form a wedge so that it is able, itself, to force a fenestration in the package or package seal, thus obviating the cutting edge.

The chest tube package may be configured with a region that allows for manipulation of the contents so that the chest tube may be advanced out of the package by manual application of force. The region permitting manipulation is an elastic area that is deformable relative to the rest of the package or it is a movable region with a sliding seal between itself and the rest of the package. Either method maintains sterility within the package during moving of the contents. The inner package containing the chest tube may also comprise a region that is specially designed to facilitate penetration by the chest tube. This penetration region is a weakened part of the heat seal or a specially designed port that opens only to permit the chest tube to penetrate the inner package.

To facilitate placement of the chest tube, a specialized cutter is configured to perform the initial incision into the chest wall without penetrating below the level of the ribs. This specialized cutter comprises safety features to prevent premature deployment and to prevent cutting too deeply into the chest. This cutter is actuated by manual, electrical or hydraulic/pneumatic force. It may be configured to be a positive displacement cutter or it may be a punch that is loaded and fired or activated under pre-determined force.

The chest tube comprises a short insertion portion (the distal segment intended and adapted for insertion into the body of the patient) and a stop to prevent it from being inserted too far into the patient. The short

insertion portion has a blunt distal end and is capable of being inserted into a fenestration or incision in the chest wall that was created by either a scalpel and blunt dissection as would be performed by a gloved finger, a  
5 Kelly clamp, or a specialized trocar and obturator. The short chest tube is inserted through the incision into the chest cavity. The short chest tube projects through the skin, fat, fascia, between the ribs, and finally through the pleural lining. The tip of the chest tube is soft or  
10 blunt or both, and contains no edges or roughness that might erode underlying tissues. The short chest tube is terminated on its proximal segment (proximal to the stop) with a manually openable and closeable valve or it is terminated with a one-way valve that permits only removal  
15 of fluids and air from the chest cavity. The short chest tube comprises a flange that prevents excessive penetration into the chest cavity. The flange is designed to stop at the level of the skin surface, or, in another embodiment, the flange is smaller and is inserted into the incision but  
20 does not penetrate below the level of the top of the ribs.

In yet another embodiment, should lateral penetration of the chest tube be desirable, the short chest tube comprises a trocar and obturator that bluntly penetrates the incision to a pre-determined depth such that it is  
25 depth-limited. The trocar further comprises a right angle turn at its distal end that serves to deflect a secondary longer chest tube that is placed through the trocar and which extends laterally in the pleural space to the desired location. The trocar and secondary chest tube comprise a  
30 seal system to prevent gas passage between the two components. The trocar further comprises an angular orientation marker that provides an indication to the

operator of the direction where the secondary chest tube will be deflected. The orientation markers may be aligned by the practitioner to point to the head or the feet (or other anatomical landmark) so that the deflection is always  
5 in a pre-determined direction.

The short chest tube may be installed on a patient by unskilled or relatively unskilled medical personnel to treat a trauma pneumothorax in the field. It cannot be placed unsafely and thus paramedics or Emergency Medical  
10 Technicians (EMTs) may install the chest tube into patients while they are in the field or the emergency department. The short chest tube is preferably coupled with a specialized blunt or automatic tissue dissector that safely dissects an incision through the ribs.

#### 15 Brief Description of the Drawings

Figure 1A illustrates a side view of a chest tube.

Figure 1B illustrates a lateral cross-section of the central area of the chest tube comprising a generally circular cross-sectional profile.

20 Figure 1C illustrates a lateral cross-section of the central area of the chest tube comprising a generally elliptical cross-sectional profile.

Figure 2A illustrates a side view of the distal tip of the chest tube with a blunt trocar or obturator in the  
25 advanced configuration so that the sharp cutter edge of the trocar is protected.

Figure 2B illustrates a side view of the tip of the chest tube with the blunt trocar or obturator in the

retracted configuration so that the sharp edge of the cutter is exposed.

Figure 2C illustrates a side view of the tip of the chest tube with the blunt trocar or obturator and the cutting blade retracted and removed back through the proximal end of the chest tube.

Figure 3A illustrates a double aseptic package around the chest tube.

Figure 3B illustrates the aseptic package with the outer layer removed.

Figure 3C illustrates the aseptic package with the chest tube advanced out through the inner layer of the package.

Figure 4 illustrates the chest tube advanced into a wound in the thoracic wall of a patient or other animal.

Figure 5A illustrates a top view of a protective wound disc.

Figure 5B illustrates a top view of the protective wound disc with its straps wrapped around and adherent to the chest tube.

Figure 6A illustrates a side view of a chest wall punch, with a retracted blade.

Figure 6B illustrates a side view of a chest wall punch with the blade advanced.

Figure 6C illustrates a bottom view of a chest wall punch with the blade advanced.



Figure 7 illustrates a side view of a chest tube, comprising a blunt trocar suitable for penetrating the package and bluntly dissecting into the chest of the patient.

5        Figure 8A illustrates a top view of a chest tube in a package comprising an integral protective wound disc and tie down straps.

10       Figure 8B illustrates a top view of a chest tube in a package comprising an integral protective wound disc and tie down straps along with an integral pleural drainage system.

Figure 9A illustrates a side view of an expandable sheath and blunt obturator.

15       Figure 9B illustrates a bottom view of the expandable sheath and blunt obturator.

Figure 9C illustrates a side view of the expandable sheath with the blunt obturator removed and a tapered expanding obturator just being inserted.

20       Figure 9D illustrates a side view of the expandable sheath with the tapered expanding obturator fully inserted so that the collet-like split sheath sides are fully expanded.

Figure 9E illustrates a bottom view of the expandable sheath with the tapered expanding obturator fully inserted.

25       Figure 10A illustrates a side view of a short chest tube, shown placed through a cross-sectional view of the outer chest wall.

Figure 10B illustrates a side view of a short deflecting trocar and chest tube placed into a thorax or chest wall of a patient.

Detailed Description of the Invention

5        Figure 1A illustrates a side view of a chest tube 10 of the present invention. The chest tube 10 comprises a length of cannula tubing 12, an optional integral valve 13, a plurality of drainage ports 14, an optional region of gripping surface 15 on the cannula tubing 12, a drainage  
10 lumen 16, a drainage connector 18, a cutter 20, a cutter handle 22, an obturator 24, an obturator handle 26 a cutter control mechanism 28, an obturator control rod 30 (see Figures 1B and 1C), and a malleable shaft 32. The cannula tubing 12 is an axially elongate hollow tube affixed at the  
15 proximal end to a drainage connector 18. The central or through lumen of the drainage connector 18 is in communication with the lumen 16 of the chest tube 10. The drainage ports 14 are penetrations communicating from the outside of the cannula tubing 12 and are in communication  
20 with the inner lumen 16. The cutter 20 is affixed to the distal end of the cutter control mechanism 28. The cutter control mechanism 28 is slideably affixed within the central or drainage lumen 16 of the cannula tubing 12. The cutter handle 22 is affixed to the proximal end of the  
25 cutter control mechanism. The obturator 24 is affixed to the distal end of the obturator control rod 30, which is slideably mounted within the drainage lumen 16 of the cannula tubing 12. The obturator handle 26 is affixed to the proximal end of the obturator control rod 30. The  
30 malleable shaft 32 is affixed to or integral to the cannula tubing 12 and runs along at least a portion of the length

of the cannula tubing 12. The obturator control rod 30 and the cutter control mechanism 28 both traverse the cannula tubing 12 from approximately its proximal end to approximately its distal end. The valve 13 is optional and is optionally configured integrally to the cannula tubing 12 or removably affixed to the drainage connector 18. The gripping surface 15 is integral to the cannula tubing 12 or it is optionally a separate structure that is movably able to grip the cannula tubing 12.

Further referring to Figure 1A, the chest tube 10 is designed to be placed within a patient's chest and into the patient's chest through an incision in the patient's chest to provide for drainage. Using additional components such as a stopcock or one-way valve 13, the chest tube prevents backflow of air or contaminants back into the chest. Such backflow of air or contaminants could lead to a pneumothorax or infection.

The valve 13 comprises a closeable central orifice that is also openable permitting the obturator control rod 30, the cutter control mechanism 28, the cutter 20 and the obturator 24 to pass therethrough. The valve 13 is either a one-way valve permitting flow only from the distal tip of the chest tube 10 and not retrograde back toward the distal tip of the chest tube 10 (a duckbill valve, for example) or a stopcock type valve (a ball valve). The valve 13 may be integral to the chest tube 10 or a separate component added proximal to the drainage connector 18.

The gripping surface 15 may be a region of roughness on the surface of the cannula tubing 12. This roughness may be created by a series of protrusions or depressions in the surface of the cannula tubing 12, or any other

texturing or knurling. The gripping surface 15 may also be a separate structure that is slidably, concentrically affixed to the cannula tubing. When the gripping surface 15 is withdrawn proximally, it slides relative to the  
5 cannula tubing 12. When the gripping surface 15 is advanced distally, it grips the cannula tubing 12 in the same manner as a jamb cleat and advances the cannula tubing 12 distally.

The materials used in the manufacture of the cannula  
10 tubing 12 of the chest tube 10 include but are not limited to polyvinyl chloride, PEBAX, polyurethane, polyester, polyethylene, PEEK, polypropylene, polytetrafluoroethylene, polyetheretherketone, fluorinated ethylene propylene, polytetrafluoroethylene-perfluoromethylvinylether and  
15 silicone rubber. In order to minimize the risk of kinking, the wall of the cannula tubing 12 may be extruded with integral spiral or braided reinforcements manufactured from materials such as but not limited to stainless steel wire, polyimide strands and the like. The cannula tubing 12 may  
20 be manufactured from materials with variable durometer or hardness. For example, the proximal end of the cannula tubing may be of harder durometer or thicker wall construction to make that area stiffer than the distal end, thus enhancing pushability and column strength of the chest  
25 tube 10.

The obturator control rod 30 and the cutter control mechanism 28 possess column strength and are inelastic in tension. The obturator control rod 30 and the cutter control mechanism 28 are, however flexible to at least some  
30 degree and allow bending of the chest tube 10 to minimize the risk of perforating internal organs on the patient

while the chest tube 10 is being inserted. The obturator control rod 30 and the cutter control mechanism 28 are fabricated from materials such as, but not limited to, stainless steel, nitinol, Elgiloy and the like. The structures of the obturator control rod 30 and the cutter control mechanism 28 are a solid or tubular axially elongate metal or, preferably, a coil or double helix or a braided reinforcement with a polymer coating or co-extrusion. Such polymer coatings include, but are not limited to, Pebax, PVC, PEEK, PTFE, PET, PETG, polyethylene, polypropylene and the like.

The interior walls of the tube 12, which form the exterior of the drainage lumen 16 and the distal ports are optionally coated with anti-thrombogenic materials to minimize the risk of thrombus. The anti-thrombogenic materials include but are not limited to heparin. The anti-thrombogenic materials are mechanically, covalently or ionically bonded to the material of the tube 12. The valve 13 and the inner lumen of the drainage connector 18 may also be coated with similar anti-thrombogenic agents. The exterior of the tube 12 as well as the interior surfaces of the chest tube 10 are optionally coated with antibiotics to minimize the risk of infection. This is especially important in contaminated environments. Such antibiotics include but are not limited to erythromycin, amoxicillin, sulfa drugs and the like.

The diameter of the cannula tubing 12 ranges from 1mm to 30mm and preferably between 2mm and 15mm. The length of the cannula tubing 12 ranges between 10cm and 200cm and most preferably ranges between 30cm and 100cm.

The malleable shaft 32 is preferably a length of stainless steel or other metal that is embedded within the wall of the cannula tubing 12. This malleable shaft may or may not be removable from the chest tube 10. The malleable shaft 32 extends along at least a portion of the cannula tubing 12 but preferably extends along the full length of the cannula tubing 12. The malleable shaft 32 is sized so that it may be bent by manual force but resists bending by resilient or elastic forces imposed thereon by the cannula tubing 12.

The drainage connector 18 is preferably fabricated from materials such as but not limited to polycarbonate, polyvinyl chloride, polyethylene, polypropylene and the like. The drainage connector 18 is preferably insert molded or affixed using adhesives to the cannula tubing 12. The drainage connector 18 preferably comprises a single through lumen. The drainage connector 18 may, however, be "Y" shaped or trident shaped and have multiple connections. Such connections typically use hose barb type fittings but may also have Luer type fittings or other bayonet or threaded connections for interface with other equipment. The drainage connector 18 is sized so that the cutter control mechanism 28 and the obturator control rod 30 may be slideably passed therethrough. The drainage connector 18, preferably is sized so that the cutter 20 and obturator 24 may be completely removed from the chest tube 10.

The cutter 20 is preferably a circular cutter with its edge beveled to the outside. A circular cutter is also known as a trephine. The plane of the front edge of the circular cutter 20 is preferably not orthogonal to the axis of the tube 12 of the chest tube 10. The plane of the

front edge of the circular cutter 20 is, preferably, disposed at an angle between 5 degrees and 60 degrees from the plane that is orthogonal to the axis of the chest tube 10.

5           Figure 1B illustrates a lateral cross-section of the central area of the chest tube 10 with the cannula tubing 12 cross-section showing the malleable shaft 32 as an integral part of the tubing. The drainage lumen 16 of cannula tubing 12 has the cutter control mechanism 28 and  
10           obturator control rod 30 running co-axially throughout the length of said lumen 16. The cross-sectional outer profile of the cannula tubing 12 is generally circular.

          Figure 1C illustrates a lateral cross-section of the central area of another embodiment of the chest tube 10  
15           with the cannula tubing 12 cross-section showing the malleable shaft 32 as an integral part of the tubing. The drainage lumen 16 of the cannula tubing 12 further comprises the cutter control mechanism 28 and the obturator control rod 30 running coaxially throughout the length of  
20           said lumen 16. The outer profile of the cannula tubing 12 is generally elliptical. An elliptical or rounded rectangular cross-sectional configuration enhances placement of the chest-tube through the intercostal space. By aligning the major axis of the ellipse with the  
25           direction of the rib disposition and the minor axis transverse to the direction of the ribs, a chest tube of larger drainage capacity than would normally be allowed by the rib spacing may be inserted between the ribs. Clamps and other devices can be used to insert a large round chest  
30           tube that would not normally fit between the ribs except by compressing, or pre-flattening, the tubing cross-section

prior to insertion. This compression technique is tedious, wastes time, requires sterile equipment and technique, and increases the chance of contamination to the patient.

Figure 2A illustrates a side view of the distal end of the cannula tubing 12 comprising the cutter 20 and obturator 24, further comprising the plurality of drainage ports 14. The cutter 20 and obturator 24 are in the extended or protected position.

Referring to Figure 2A and 1A, the cutter 20 is blunted or protected by the extended obturator 24 so that the sharp edge or sharp tip of the cutter 20 cannot inadvertently cut through the sterile packaging of the chest tube 10. Such blunting or protection of the cutter 20 by the obturator or blunt tip 24 is selective or controllable. The cutter control mechanism and obturator control rod thus provide means for longitudinally translating the cutter relative to the obturator, so that it may be selectively extended to put the cutting edge distal of the obturator. The means for longitudinally translating the cutter may also be implemented such that the obturator is longitudinally fixed relative to the cannula tubing, in addition to the longitudinally slidable obturator illustrated in the figures..

Figure 2B illustrates a side view of the distal end of the cannula tubing 12 comprising the cutter 20 and obturator 24, further comprising the plurality of drainage ports 14. The cutter 20 is in the extended position while the obturator 24 slightly retracted.

Referring to Figure 2B, the obturator 22 is slightly retracted to expose the sharp edge of the cutter 20. The



sharp edge of the cutter 20 is now useable to punch through the packaging of the chest tube to facilitate using the tube in emergency conditions or contaminated environments.

Figure 2C illustrates a side view of the distal end of the cannula tubing 12 comprising the plurality of drainage ports 14. Referring to Figures 1A and 2C, the cutter 20 and obturator 24 are not visible in this view, as they have been removed from the cannula tubing 12 to open the drainage lumen 16 in order to perform the designed function of the chest tube 10.

Figure 3A illustrates the packaging 40 of the present invention. The packaging 40 contains the chest tube 10, and comprises an outer package 42 and an inner package 44. The outer package 42 and inner package 44 are sterile barriers for the chest tube 10. The inner package 44 and the outer package 42 are, preferably, polyethylene pouches that are closed using heat seals. The heat seals are typically from 1/8 inch to 1/2 inch wide around the perimeter of the pouches. The pouches may have regions fabricated from sterile barrier such as Tyvek that is suitable for use with ethylene oxide (ETO) sterilization and allows said ETO to pass into the pouch but prevents contamination from entering the pouch. The weakened area of the seal can be an area where the seal is less wide (1/8 to 1/16 inch) than the rest of the seal.

In another embodiment, the outer package 42 is a tray fabricated from materials such as but not limited to polystyrene, polyvinyl chloride, PETG and the like. The trays are typically thermoformed and are covered with a lid fabricated from Tyvek, PETG, polyethylene or the like. The lid is preferably heat sealed to a flange at the open end

of the tray. A tray is advantageous over a pouch in that it offers protection against crushing that is not provided by the pouch. The tray, however, is larger, heavier, and more difficult to store and dispose.

- 5           The double sterile barrier is intended to give the practitioner the option of not using the device after initial assessment of the patient and also for cleanliness and sterility purposes in the field.

10           Figure 3B illustrates the packaging 40 with the outer package 42 removed. The inner package 44, further comprising a gripping region 48, is still sealed and protects the chest tube 10 from contamination. The gripping region 48 provides an area on the package where the operator may more easily grab the chest tube 10 without  
15           slipping. This gripping region 48 is a high friction region relative to the rest of the package. The gripping region 48 is, in a further embodiment, elastomeric in structure and allows the operator to advance the chest tube 10 while the flexible or inflexible, but inelastic, inner  
20           package 44 remains relatively undistorted and stable. Suitable materials for fabricating the gripping region 48 include, but are not limited to, polyurethane, silicone rubber, thermoplastic elastomers such as C-Flex, and latex rubber.

- 25           In yet another embodiment, the gripping region 48 is movably attached to the inner package 44 by means of a sliding or moving seal. This sliding or moving seal is a gasket between the gripping region 48 and the inner package 44 that prohibits passage of contaminants into the inner  
30           package 44 but still permits translation or movement of the gripping region 48 relative to the inner package 44. In

one exemplary embodiment, the gripping region 48 includes a plunger that impinges on the friction surface 15 on the chest tube 10. The operator depresses the plunger or gripping region 48 and the chest tube 10 is forced against  
5 and through the inner package 44 seal at seal penetration point 46.

Figure 3C illustrates the packaging 40 of the chest tube 10 in the inner package 44, further comprising the gripping region 48, with the obturator handle 26 in the  
10 partially retracted position. The chest tube 10 in this configuration will allow inner package seal penetration 46 to occur as a result of advancement of the chest tube 10 with the cutter 20 exposed, thus penetrating the inner package 44 seal. The obturator 24 is not visible in this  
15 view as it is retracted into the cutter 20 and cannula tubing 12. This allows for cutter 20 penetration through the inner package 44 at the seal penetration point 46 to maintain sterility until advancement and deployment into the patient.

20 In another embodiment of the invention, the inner package 44 seal is weakened at a specific area where the chest tube is intended to penetrate the seal. This weakened area is, preferably, visibly marked with indicia adequate to inform the practitioner of the location of the  
25 weakened area (and, thus, the preferred point of exit) to ensure that the chest tube penetrates the seal at the weakened area of the inner package 44. In yet another embodiment, an openable window is provided in the inner package 44 where the chest tube is to be advanced out of  
30 said inner package 44. This openable window is, for example, a normally closed elastomeric valve (a duckbill or

slit membrane) that is pried open by the chest tube obturator or its cutter. An optional thin seal layer is used to maintain sterility over the openable window, prior to opening.

5           Figure 4 illustrates the method of installing the device 50 into a patient. The chest tube 10 is contained in a sterile inner package 44 until ready for deployment into patient 52 through an incision site 54. The access site is first prepared by swabbing or rinsing the area with  
10   betadine or other disinfectant, preferably using standard hospital or emergency procedures. The adhesive patch described below or other flexible structure further comprising a disinfectant is applied to the region of the incision. An incision is made in the chest wall using a  
15   sterile scalpel, punch or other device. A finger or, alternatively, other blunt device is next advanced through the incision to bluntly dissect through the final layers of chest wall into the chest cavity. The blunt device for dissection may optionally be comprised at the distal tip of  
20   the chest tube itself. To deploy the chest tube from its protective package, the user first opens and removes the outer sterile or aseptic packaging layer, maintaining the inner package substantially intact, so that the chest tube can be placed without the need for sterile gloves to be  
25   worn by the user. Next, the user grasps the chest tube and the blunt trocar control knob through the inner layer of flexible packaging. The blunt trocar is manually retracted within the cannula exposing the sharpened distal tip of the cannula. The cannula is punched through the inner layer of  
30   package by way of the sharp tip and the blunt trocar is now replaced to its protective position. The chest tube is now advanced into the prepared incision in the chest cavity.

During deployment, the inner package is left intact over the chest tube, while only the distal end of the tube extends out of the package, ensuring sterility of the chest tube to the maximum extent possible.

5        Figure 5A illustrates an aseptic hold-down patch 60 to be used with the chest tube. The aseptic hold down patch 60 comprises a penetration region 62, a main adhesive region 64, a hold down plate 66, a plurality of hold down straps 68, an adhesive region 70 on each strap, a plurality  
10 of pull tabs 72, and a plurality of partially completed slits 74 within the penetration region 62. As illustrated, the patch is a disc, but it may be provided in any suitable shape.

Referring to Figure 5A, the main adhesive disc 64 is  
15 permanently affixed to the hold-down disc 66 with adhesive or other fasteners. The hold down-straps 68 are affixed to or integral to the hold-down disc 66. The adhesive region 70 is on the hold-down strap 68 and the pull-tab 72 is at the end of the hold-down strap 68. The penetration region  
20 62 is at the center of both the main adhesive disc 64 and the hold down disc 66. The penetration region 62 comprises slits or score lines 74 that pass partially, but not completely, through from the outside. The slits 74 may also advantageously fully penetrate the main adhesive disc  
25 64 and the hold down disc 66. The central area around the penetration region 62 is preferably transparent or clear, to permit viewing of the incision site while the hold down disc 66 and main adhesive disc 64 are being advanced against the patient. The hold down disc 66 and the backbone  
30 structure of the main adhesive disc 64 are fabricated from materials including, but not limited to, cardboard,

polystyrene, polyvinyl chloride, polyester, polyimide, polyamide, polyethylene, polypropylene, and the like, and they may be integrally formed. While the hold down disc 66 and the main adhesive disc 64 should be semi-rigid or have reduced flexibility, the hold down straps 68 are preferably of greater flexibility. The flexibility can be achieved by weaving or knitting structures of the polymers such as polyester cloth and the like.

The adhesive region 70 is designed to be fastened to the chest tube to hold the chest tube from being dislodged from the patient. The adhesive region 70 may alternatively be fabricated using Velcro or other fastener systems that mate with corresponding systems attached to the chest tube 10. If adhesives are used in the adhesive region 70, a paper or plastic cover strip, removable before use, is desirable to protect the adhesive.

The main adhesive disc 64 is coated, on the patient side, with a strong skin adhesive. Such adhesives include cyanoacrylates, but preferably include aggressive adhesives that may be removed or un-adhered such as those adhesives that are used on the pads of electrocardiogram (EKG) electrodes. The adhesive may optionally comprise antigenic, antibiotic or anti-microbial agents such as, but not limited to, silver azide, silver chloride and the like. The adhesive region is, preferably, covered with a plastic or paper cover that is removed by the practitioner, prior to adhering the disc to the patient. Prior to adhesion of the hold down disc 60 to the patient, the practitioner preferably scrubs the area with betadine or other antimicrobial agent using standard aseptic technique.

Figure 5B shows the hold-down disc 60 adhered to the patient 50. The hold down straps 68 are wrapped around and adhered to the chest tube 10, holding the chest tube 10 in place. The cutter handle 22 and obturator handle 26 are  
5 not visible in Figure 5B because they have been removed from the chest tube 10.

Figure 6A illustrates an incision apparatus 100, with its cutter retracted. The incision apparatus 100 comprises a cutting blade 102, a shaft 104, a chest plate 106, a  
10 bearing 108, a housing 110, a spring 112, a handle 114, a travel stop 116, a locking mechanism 118, and a lock extension 120.

Referring to Figure 6A, the cutting blade 102 is permanently affixed to the distal end of the shaft 104  
15 while the handle 114 is permanently affixed to the proximal end of the shaft 104. The shaft 104 slideably moves through bearing 108 that is permanently affixed to the housing 110, which is further affixed to the chest plate 106. The spring 112 biases the shaft 104 so that the  
20 cutting blade 102 is retracted within the housing 110. The travel stop 116 is affixed to the housing 110 and limits travel of the handle 114. The locking mechanism 118 is affixed to either the chest plate 106 or the housing 110. The locking mechanism is affixed to the lock extension 120.  
25 The lock extension 120 selectably engages the cutter 102 to prevent inadvertent advancement of said cutter 102 until desired.

The cutting blade 102 is preferably fabricated from stainless steel and is configured to form a cross or X.  
30 The cutting blade 102 may also be a single blade or other

configuration. The cutting blade 102 may be pointed or rounded in side view.

The spring 112 is preferably a concentric coil spring fabricated from stainless steel, Elgiloy, nitinol or other  
5 suitable spring material. The spring 112 can also be a leaf spring or have a non-concentric configuration.

The chest plate 106, the housing 110, the handle 114, the locking mechanism 118, the lock extension 120, and the travel stop 116 are fabricated from polymeric materials  
10 including as but not limited to PVC, polycarbonate, acrylic, Delrin, polypropylene, PEEK or other suitable rigid material. The chest plate 106 is preferably transparent and may be provided with an adhesive on the skin contacting surface 107.

15 Referring to Figure 6A, the chest plate 106 is placed against the chest of the patient so that the center of the chest plate 106 is at the desired incision point. The chest plate 106 is held against the chest of the patient and the locking mechanism 118 is disengaged. Manual force  
20 is applied to the handle 114, which advances the cutter 102 until such point as the handle 114 hits the travel stop 116. Release of manual pressure from the handle 114 causes the spring 112 to retract the blade 102 back within the housing. The incision apparatus is designed to cut through  
25 only the skin, fascia, and fat of the patient and limit deeper advancement of the blade. The travel stop 116 prevents the blade 112 from penetrating lower than the level of the ribs, so as to avoid damage to underlying organs.



Figure 6B illustrates a side view of an incision apparatus 100 with its cutter advanced. The incision apparatus 100 comprises a cutting blade 102, a shaft 104, a chest plate 106, a bearing 108, a housing 110, a spring 112, a handle 114, a travel stop 116, a locking mechanism 118, and a lock extension 120. The locking mechanism 118 has been withdrawn permitting the cutting blade 102 to be forced beyond the face of the chest plate 106 and into the patient. The handle 114 is now impinging on the travel stop 116 to prevent the cutting blade 102 from being advanced too far beyond the chest plate 106 and thus injure the patient. The spring 112 is compressed to provide biasing of the cutting blade 102 away from the patient after the force on the handle 114 is removed.

Figure 6C illustrates a bottom view of an incision apparatus 100. The cutting blade 102 is clearly shown with an "X" configuration in this embodiment. The shaft 104 and the bearing 108 are visible in this view.

Figure 7 illustrates another embodiment of the chest tube 10. The chest tube 10 comprises a length of tubing 12, an optional valve 13, a plurality of distal openings or drainage ports 14, an optional gripping or friction surface 15, a central lumen 16, a drainage connector 18, an obturator 24, an obturator handle 26, and an obturator control rod 30. The length of tubing 12 comprises a wall and a central lumen 16. The openings 14 are holes extending through the tubing wall from the exterior to the central lumen 16. The optional valve is affixed integral to or separate from the tubing 12. The friction surface 15 is integral to the tubing 12 but may be a separate structure slidably disposed over the tubing 12. The

drainage connector 18 is affixed to the proximal end of the tubing 12. The obturator 24 is slidably disposed within the central lumen 16 of the tubing 12. The obturator 24 is affixed to the distal end of the obturator control rod 30.

5 The obturator handle 26 is affixed to the proximal end of the obturator control rod 30 and extends outside the drainage connector 18.

The obturator 24 could also be termed a nose cone, blunt trocar or other designation. The obturator 24 is wedge shaped but could alternatively be symmetrical in configuration. The obturator 24 is not sharp enough to cut through skin under pressures up to 20 pounds. The obturator 24 is, however, able to optionally bluntly dissect muscle and pleural tissue under forces of  
10 approximating 20 pounds. The obturator 24 is removed from the chest tube 10 by grasping the obturator handle 26 and withdrawing said obturator handle 26, which removes the obturator 24 by withdrawing the attached obturator control rod 30. The obturator control rod 30 possesses column  
15 strength and resistance to elongation under tension but is flexible to at least some degree. This flexibility permits the obturator control rod 30 and the chest tube 10 to bend during insertion into the patient, thus minimizing the risk of internal organ perforation. The obturator control rod  
20 30 optionally possesses variable flexibility. It is preferred that the obturator control rod 30 is more flexible toward the distal end and less flexible toward the proximal end. Referring to Figures 1B, 1C and 7, this embodiment of the chest tube 10 may also comprise a  
25 malleable shaft 32.  
30

Figure 8A illustrates a packaged chest tube system 150 comprising an axially elongate cannula tube 152 with a central lumen (not shown), a plurality of distal openings 154, an optional one-way valve 156, an optional shutoff valve 158, a connector 160, an obturator further comprising a shaft 162 and a handle 164, a trocar further comprising an axially elongate cylindrical shaft 166, a beveled tip 168, and a limit stop 170, an inner pouch 172 further comprising a plurality of chevron opening regions 176, a hold down disc 178 further comprising a protective cover sheet (not shown), a central slit region 180, a substrate with a clear window area 182 a plurality of hold down ties 184 each further comprising a cannula grip region 186, and a skin adherence region (not shown), and an outer pouch 188 further comprising a plurality of chevron opening areas 190, and labeling (not shown).

Referring to Figure 8A, the cannula tube 152 is an axially elongate tube with a central through lumen having a proximal and a distal end. The distal end of the cannula tube 152 comprises a plurality of perforations, penetrations, or holes 154 that communicate between the exterior of the cannula 152 and the central lumen. The proximal end of the cannula tube 152 is permanently or removably affixed to the one-way valve 156 and further removably affixed, preferably in series, to the shutoff valve 158 as well as the connector 160. The shaft 162 of the obturator is removably, and slidably placed through the central lumen of the cannula tube 152. The obturator handle 164 is permanently affixed to the shaft 162 and projects out the proximal end of the cannula tube 152 and any attachments including the connector 160. The axially elongate shaft 166 of the trocar is concentrically,

slidably, and movably placed over the cannula tube 152. The trocar shaft 166 is sharpened and preferably beveled on its distal end 168. The proximal end of the trocar shaft 166 is permanently affixed to the limit stop 170, which  
5 further comprises a central through lumen and slidably moves over the cannula tube 152.

Further referring to Figure 8A, the outer pouch 188 is preferably comprised of an upper layer and a lower layer not shown. The upper layer and the lower layer are  
10 preferably heat sealed together so as to form a complete barrier against microbial contaminants. The band where the upper layer is sealed to the lower layer is called the heat seal 214. The outer pouch 188 preferably comprises one or more openable areas, or chevrons 190, that are comprised by  
15 heat seals that are disposed diagonally across the corners of the outer pouch 188 to permit a user to grab the upper layer separately from the lower layer and tear the two layers apart at the chevron 190. The outer pouch 188 further preferably comprises a label, which is either  
20 integral or adhered to the outer pouch 188. The inner pouch 172 is fabricated using similar techniques as the outer pouch 188. Preferably the inner pouch 172 comprises an upper and a lower layer that are heat sealed together with opening chevrons 176 and heat seals 212. The inner  
25 pouch 172 further comprises a hold down disc 178 that is permanently affixed, removable, or integral to the distal end of the inner pouch 172. The hold down disc 178 is fabricated from a substrate 182 that forms the main body of the hold down disc 178. The substrate 182 is coated on the  
30 distal most side with an adhesive that is skin compatible and preferably adheres to wet skin. The substrate 182 further comprises a window area, which is a clear or

transparent region permitting visibility through the hold-down disc at least in its central region. The substrate 182 is partially, or completely perforated at its central region in, for example, a cross or "X" shape, to permit  
5 easy penetration of the hold-down disc by the distal tip of the cannula 152. The hold-down disc 178 is preferably folded flat so as to be insertable into the outer pouch 188 with a minimum profile. The hold-down disc 178 further is permanently affixed to one or more tie down straps 184 that  
10 further are coated with adhesive near the ends to form adhesive regions 186. The tie-down straps 184 are disposed within the interior of the inner pouch 172. They may be separate or pre-attached to the cannula 152. If separate, the adhesive regions 186 of the tie down straps 184 are  
15 covered by a protective peel-away layer (not shown).

The hold-down disc 178, in another embodiment, is a flexible, elastomeric, rigid or semi-rigid piece of polymer, metal, or the like and is configured with a soft, pliable exterior edge. The hold-down disc 178, in this  
20 embodiment, is a suction cup that adheres to the patient's skin by way of suction. A port, valve, and suction bulb for manual evacuation are optionally beneficial to this embodiment in that they can be used to enhance the vacuum bond created by the basic suction cup design.

25 The hold down disc 178 is, preferably, affixed to or integral to the inner pouch 172 and the proximal side of the hold down disc 178 comprises part of the interior of the inner pouch 172. Because the inner pouch 178 is flexible, the hold-down disc 178, which is normally in the  
30 plane orthogonal to that of the inner pouch 172 or the cannula 152, may be turned sideways so that it resides in a

generally coplanar disposition relative to the inner pouch 178 and cannula 152 during packaging, shipping, and storage.

The trocar comprised by the shaft 166, the limit stop 5 170 and the sharpened end 168 is very short. The trocar is intended to be forced into a skin incision made in the patient's chest. The trocar cannot penetrate very far because the distance between the sharpened end 168 and the distal end of the limit stop 170 is limited. In a 10 preferred embodiment, the limit stop 170 is large in diameter and stops against the outside of the skin. The diameter of the limit stop 170 is between 1 and 20 cm, and preferably between 2 and 10 cm and more preferably between 3 and 6 cm. The length of the shaft 166 is between 1 and 15 10cm and preferably between 2 and 5cm. The length of the shaft 166, in this embodiment, will need to be tailored to the individual because each person has a different amount of fat so different sizes may be required, for example, large, medium, and small. Thus, the distal segment of the 20 cannula which enters the body may be provided in various predetermined lengths to suit patients of varying physique, and the practitioner may select a suitably short device for use after appraisal of the patient.

In another embodiment of the trocar, the limit stop is 25 smaller in diameter and stops against the outside of the ribs. In this latter embodiment, the limit stop 170 is passed inside a skin incision and through fat layers so that it stops at or near the outer region of the ribs. The diameter of the limit stop 170 in the latter embodiment is 30 between 1 and 5 cm and preferably between 1 and 3cm. The length of the shaft 166 is between 1 and 5cm and,

preferably between 1.5 and 4cm so that it passes through the ribs and into the pleural space but does not project far into the pleural space. This embodiment avoids much of the issues with regard to amount of body fat on a person and allows for a one-size-fits-all approach, so that the distal segment of the cannula may be provided in a single predetermined length suitable for safe, stop-limited penetration through the rib cage.

Figure 8B illustrates a packaged chest tube system 200 comprising an axially elongate cannula 152 with a central lumen (not shown), a plurality of distal openings 154, an optional one-way valve 156, an optional shutoff valve 158, a connector 160, a trocar further comprising an axially elongate cylindrical shaft 166, a beveled tip 168, and a limit stop 170, an inner pouch 202 further comprising an upper layer and a lower layer (not shown), a plurality of heat seals 212, a drainage volume 204, a drainage inlet manifold 206, an optional vacuum port 208, an optional stopcock 210, an optional vacuum pump (not shown), a hold down disc 178 further comprising a protective cover sheet (not shown), a central slit region 180, a plurality of hold down ties 184, a substrate with a clear window area 182, and a skin adherence region (not shown), and an outer pouch 188, further comprising an upper layer and a lower layer (not shown), a plurality of heat seals 214, a plurality of chevron opening areas 190, and labeling (not shown).

The embodiment of Figure 8B is similar to that of Figure 8A, except that the inner pouch 202 comprises the drainage volume 204, the drainage inlet manifold 206, the optional vacuum port 208, the optional stopcock 210, and the optional vacuum pump. These components are either

integral to the inner pouch 202 or are affixed and bonded to the inner pouch 202 using heat, solvents, adhesives, ultrasonic welding, or the like. Referring to Figure 8A, the cannula 152 of Figure 8B does not comprise an obturator shaft 162 or handle 164, although these could be added, if  
5 desired. In this embodiment, the extreme distal tip of the cannula 152 is advantageously of increased stiffness, or has decreased flexibility, relative to the rest of the shaft 152. In this way, by careful location of the distal  
10 tip of the cannula 152 relative to the trocar shaft 166 and sharpened end 168, the cannula 152 serves the function of the blunt obturator.

Referring to Figure 8B, the drainage volume 204 serves as an integral collection device, much like a pleur-evac.  
15 The drainage volume 204 is connected to the connector 160 of the cannula 152 by way of the drainage manifold 206. The drainage volume may comprise an optional standoff to maintain a finite internal volume for maintenance of a pre-applied or generally applied vacuum. The vacuum pump may  
20 be a simple manual bulb or it may be any of the typical manual or electromechanical devices available.

Further referring to Figures 8A and 8B, the method allows for placement of a chest cannula 152 in a patient without the need to use gloves since the cannula 152 and  
25 any associated apparatus is handled through the protective pouches or bags. The entire system is sterilized. The chest tube 152 and its components, and the inner pouch 202, both inside and outside, are maintained sterile by the outer pouch 188. The patient incision site is first  
30 swabbed with iodine, betadine, or other disinfectant. An incision is made, with a sharp blade, through the skin and



into the fat layers. After removal of the outer pouch 188, the chest tube or cannula 152 may be manipulated through the inner pouch 202. The hold down disc 178 is adhered to the skin at the incision site. The trocar and

5 concentrically mounted chest tube 152 are forced through the central slits 180 in the hold-down disc 178 and into the incision. The trocar is forced into the incision until the limit stop 170 hits the hold down disc 178. The trocar is withdrawn and the chest tube cannula 152 is advanced

10 into the incision. Once placement is acceptable, the tie down straps 186 are wrapped around the cannula shaft 152 and chest drainage management can commence.

Figure 9A illustrates an expandable trocar 250 comprising a limit stop 252, a plurality of split sleeves

15 254, an obturator stop 256, an obturator handle 258, and an obturator shaft 260.

Referring to Figure 9A, the plurality of split sleeves 254 are disposed concentrically at their minimum potential diameter. The split sleeves 254 are embedded in or affixed

20 to elastomeric or malleable material that is affixed to a central lumen of the limit stop 252. The obturator shaft 260 is preferably rounded at its distal end and is affixed to the obturator stop 256, which is further affixed to the obturator handle 258. The obturator shaft 260 is movably,

25 removably, and slidably disposed within the central lumen described by the split sleeves 254. The rounded distal end of the obturator shaft 260 is positioned so that when the obturator stop 256 is against the proximal side of the limit stop 252, the rounded section fully projects beyond

30 the distal end of the split sleeves 254.

The number of split sleeves 254 is between 2 and 100, and preferably between 4 and 50, and more preferably between 6 and 20.

The region between the split sleeves 254 is either  
5 open or it is filled in with an elastomeric material such as, but not limited to polyurethane, silicone elastomer, thermoplastic elastomer, latex rubber, polyethylene foam, polyvinyl chloride foam, polyurethane foam, and the like.

Figure 9B illustrates a bottom view of the expandable  
10 trocar shown in Figure 9A, further comprising the obturator shaft 260, the plurality of split sleeves 254, the limit stop 252, and the expandable region 262.

Referring to Figures 9A and 9B, the limit stop 252 as well as all components of the obturator are preferably  
15 fabricated from metals such as, but not limited to, stainless steel, cobalt nickel alloys, nitinol, or titanium, or polymeric materials such as, but not limited to, polyethylene, polypropylene, polycarbonate, polyester, polyvinyl chloride, ABS, and the like. The elastomeric or  
20 malleable material, in which the split sleeves 254 are embedded, is preferably a material such as, but not limited to polyurethane, silicone elastomer, thermoplastic elastomer, latex rubber, polyethylene foam, polyvinyl chloride foam, polyurethane foam, and the like. The split  
25 sleeves 254 are fabricated from materials such as, but not limited to, stainless steel, cobalt nickel alloys, nitinol, or titanium, and the like. The elastomeric region in the limit stop 252 embeds the split sleeves 254 and allows them to expand under the force of a tapered obturator or central  
30 insertable mass. In another embodiment, the elastomeric region 262 is replaced by cantilevered split sleeves 254

that are embedded into the limit stop **252**. The split sleeves **254** are leaf springs and expand in the presence of a large insertable central mass.

Figure 9C illustrates the expandable trocar **250** of  
5 Figure 9A with the obturator components **260**, **256**, and **258** removed and a large expanding obturator **270** being inserted. The large expanding obturator **270** further comprises a tapered region **272**, a blunt rounded tip (not shown), a straight shaft **274**, and an expanding obturator handle **276**.  
10 The expanding obturator **270** has not been inserted far enough to cause any expansion of the split sleeves **254**.

Figure 9D illustrates the expandable trocar **250** with the large expanding obturator **270** having been fully inserted therein. The split sleeves **254** have opened up  
15 forming a series of fingers that are intended to pry open or expand tissue. The blunt tip **278** of the expanding obturator **270** is visible in this view. It is preferable that the blunt tip **278** not project beyond the distal ends of the split sleeves **254** but a small amount of projection,  
20 as shown, is acceptable.

Figure 9E illustrates a bottom view of the expandable trocar **250** with the large expanding obturator **270** having been fully inserted therein. The elastomeric or malleable region **262** has become much narrower than in the unexpanded  
25 state of Figure 9B, due to the expansion of the embedded split sleeves **254**.

Referring to Figures 9A through 9E, the expandable trocar permits placement of a small diameter trocar through the thoracic wall, a procedure which is fairly commonplace  
30 and easy. However, by removal of the small obturator and

full insertion of the large expanding obturator 270, the trocar 250 and the hole in the tissue it supports is expanded greatly and in such a way that a chest tube could be inserted therethrough. In yet another embodiment of the

5 expandable trocar 250, the obturator shaft 260 is sharpened and capable of cutting through the skin, fat, fascia, and muscle of the patient. The sharp tip on the obturator shaft 260, in this embodiment would be retracted automatically by standoffs that projected distally of the

10 limit stop 252 and were attached to the obturator stop 256 or obturator handle 258. Automatic retraction of the sharp tip of the obturator shaft 260 would permit a one-step procedure or method to punch a hole in the thoracic wall and insert the trocar 250 through the ribs to the limit

15 stop 252 without the need of a scalpel or other sharp object to make the initial skin incision.

Figure 10A illustrates a short chest tube 300 comprising a cannula tube 302, a plurality of drainage holes 314, a limit stop 304, a tube standoff 306, a one-way

20 valve 308, a stopcock 310, and a drainage connector 312. The short chest tube 300 is shown inserted through an incision through a skin 320, a fat layer 322, a layer of fascia 330, a region of intercostal muscle 324, between the ribs 326, through the pleura 328, and into the pleural

25 space 332.

Referring to Figure 10A, the cannula tube 302 is an axially elongate hollow tube with a proximal and a distal end. The proximal end of the cannula tube 302 is affixed to the limit stop 304, which is affixed to the tube

30 standoff 306, which is affixed to the one-way valve 308, which is affixed to the stopcock 310, which is affixed to

the distal end of the drainage connector 312. A central through lumen is maintained from the distal end of the cannula tube 302 to the proximal end of the drainage connector 312 so that fluid can be drained from the thoracic cavity. The one-way valve 308 prevents backflow into the thoracic cavity but opens to provide a through lumen for drainage. The stopcock 310 provides manual shutoff or opening of the through lumen. The drainage holes 314 communicate between the through lumen and the outside of the cannula tube 302. The plurality of drainage holes 314 are provided since a single hole, at the distal tip for example, might become occluded with tissue and drainage could not occur. The plurality of holes 314 separated by the material of the cannula tube 302 provides a standoff for the tissue and maximizes the surface area for drainage of the pleural space.

Referring to Figure 10A, the short chest tube 300 may be forced between the ribs 326 and into the pleural space 332 with reduced risk of damage to internal organs since the distal end of the cannula tube 302 is rounded and blunt. In addition, the length of the cannula tube 302 is short so that it projects just a small amount into the pleural space 332. The cannula tube 302 is provided, for example in several lengths to accommodate people with different thicknesses of body fat. The diameter of the cannula tube 302 is between 0.25cm and 4cm and preferably between 0.5cm and 2 cm. The limit stop 304 prohibits the short chest tube 300 from being advanced too far into the patient and, thus, minimizes the risk of damage to the underlying organs such as the heart and lungs. The lengths and diameters of the limit stop 304 and the construction

materials is the same as that described for the trocar 250 shown in Figures 9A through 9E.

Figure 10B illustrates a short deflecting trocar and chest tube system 350 where the trocar comprises a trocar tube 352, a deflecting tip 354, a limit stop 356, and a sealing handle 358. The chest tube comprises a cannula 360, a plurality of drainage holes 362, an optional obturator shaft 364 and an optional obturator handle 366, a one-way valve 368, a stopcock 370, and a drainage connector 372. The short deflecting trocar and chest tube system 350 is shown inserted through an incision through a skin 320, a fat layer 322, a layer of fascia 330, a region of intercostal muscle 324, between the ribs 326, through the pleura 328, and into the pleural space 332.

Referring to Figure 10B, the short deflecting trocar and chest tube system 350 permits placement of a short trocar through the ribs and into the pleural space. A chest tube cannula 360 is then inserted therethrough and deflected so that it can route parallel to the plane of the chest wall to a desired location. The obturator shaft 364 and the obturator handle 366 are preferably omitted from the system but may advantageously be added if additional column strength or steerability is desired.

The trocar sealing handle 358 is fabricated from rigid polymers such as, but not limited to ABS, PVC, polyethylene, polypropylene, polysulfone, polycarbonate, and the like, and further comprises a central lumen with an elastomeric seal through which the cannula shaft 360 may slidably and movably pass but which seals and prevents the passage of air or liquid around said cannula shaft 360. The elastomeric seal (not shown) is fabricated from

materials such as, but not limited to, silicone elastomer, latex rubber, thermoplastic elastomer, polyurethane, and various closed-cell or open-cell foams. The inner surface of the elastomeric seal is advantageously coated with a  
5 lubricant such as silicone oil, or the like, to facilitate movement of the cannula shaft 360 through the sealing handle 358.

Referring to Figure 10C, the limit stop 304 is sized and dimensioned to permit advancement through the fat layer  
10 322 overlying the patient's rib cage, but prevent advancement into the narrow space between the ribs 326. In this arrangement, the length of the tube 302 distal to the stop is set at a predetermined length corresponding to the average thickness of the ribs, so that the distal tip of  
15 the tube extends into the pleural space 332 without significant risk of injuring tissue therein. In all other respects, the chest tube may be similar to the chest tubes of the previous figures.

The advantage of the aforementioned devices and  
20 methods improves the ease with which a chest tube may be placed, especially by less well-trained personnel such as paramedics and emergency medical technicians.

Application of the chest tube system provides improved speed of application of the chest tube, especially in  
25 contaminated environments. The application of this chest tube system facilitates damage control procedures wherein the patient can be allowed to stabilize prior to definitive repair of the injuries. The aseptic hold-down disc and the incision apparatus allow for quicker application of the  
30 chest tube by paramedics and emergency personnel with less

chance of wound contamination, internal damage to the patient or chest tube dislodgement.

The present invention may be embodied in other specific forms without departing from its spirit or  
5 essential characteristics. For example, the aseptic hold  
down disk may have more than two straps to restrain the  
chest tube. The incision apparatus may have a cocking  
mechanism to retract and then fire the cutter, rather than  
using positive hand pressure to advance the cutter. The  
10 described embodiments are to be considered in all respects  
only as illustrative and not restrictive. The scope of the  
invention is therefore indicated by the appended claims  
rather than the foregoing description. All changes that  
come within the meaning and range of equivalency of the  
15 claims are to be embraced within their scope.